

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MONSANTO COMPANY,
MONSANTO TECHNOLOGY LLC
Plaintiffs,

vs.

E.I. DUPONT DE NEMOURS AND,
COMPANY and PIONEER HI-BRED
INTERNATIONAL
Defendants.

Case No. 4:09CV00686 ERW

FILED UNDER SEAL

MEMORANDUM AND ORDER

PER COURT'S ORDER OF REDACTION - Pages 1-6 thru line 18 remain sealed.

Monsanto's Motion to Exclude All Evidence Regarding Defendants' Hatch-Waxman Safe Harbor Defense [ECF No. 1346]

The safe harbor provision of the Hatch-Waxman Act states:
It shall not be an act of infringement to make, use, offer to sell, or sell within the United States . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

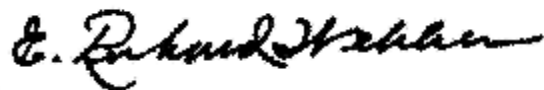
35 U.S.C. § 271(e)(1). The purpose of the safe harbor provision “is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity, which will begin after a valid patent expires, is not patent infringement.” *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1071(Fed. Cir. 2011) (quoting H.R. Rep. No. 98-857, pt. 1, at45, 1984 U.S.C.C.A.N. 2647,2678 (1984)). “Every decision examining the statute has appreciated that § 271(a)(1) is directed to premarketing approval of generic counterparts before patent expiration.” *Id.* Defendants claim that the defense applies even though they are not seeking approval of a generic of a patented drug product or medical device.

Defendants argue for a broad interpretation of the safe harbor provision by relying on language from *Merck KGaA v. Integra Lifesciences I, Ltd.*,: “it [is] apparent from the statutory text that § 271(e)(1)’s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.” 545 U.S. 193, 202 (2005). Defendants take this statement out of context. In *Merck*, the Supreme Court stated this language before explaining that the phase of research or the type of submission did not limit the protections of the provision. *Id.* *Merck* does not expand the coverage of the safe harbor provision beyond pharmaceuticals and medical devices.

Under *Classen*, *Merck*, and the facts of this case, the Hatch-Waxman safe harbor defense does not apply. Allowing Defendants to invoke this defense would be an expansion of the Federal Circuit’s and the Supreme Court’s interpretation of the provision. Monsanto’s Motion, therefore, will be granted.

PER COURT’S ORDER OF REDACTION - Page 7, line 18 thru Page 27, line 10 remain sealed.

Dated this 29th day of June, 2012.



E. RICHARD WEBBER
SENIOR UNITED STATES DISTRICT JUDGE